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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,586	11/14/2003	Timothy J. Patrick	14.012011	1671
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CYTYC CORPORATION				
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MARLBOROUGH, MA 01752				
EXAMINER				
LACYK, JOHN P				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
05/29/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/714,586

**Applicant(s)**

PATRICK ET AL.

**Examiner**

John P. Lacyk

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 7-28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-28, 31-33 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-28, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (5,429,582) in view of Tam et al (6,458,069).

Williams discloses a brachytherapy device for treating tissue surrounding a resected cavity having a catheter body member having proximal and distal portions and an expandable member that defines a spatial volume. The volume is configured to receive a radiation source that would inherently provide a three-dimensional isodose profile that is substantially similar in shape to the expandable surface member. The embodiment as shown in Figure 7 further includes a treatment agent that is delivered to adjacent tissue when the device is positioned within the tissue cavity. Williams discloses the claimed device and method except for the treatment agent being releasably mated with the expandable surface member. Tam et al discloses a similar device that provides radiation therapy to a site in a body lumen having a catheter body member having proximal and distal portions and an expandable member that defines a spatial volume. Tam et al also teaches that a treatment agent is releasably mated with the expandable member, by coating or disposing the treatment agent on all or a portion of the outer surface and the inner surface of the expandable member (column 17, lines 56-67). Therefore a modification of Williams such that the treatment agent is coated onto the

expandable member to deliver the treatment agent would have been obvious to one skilled in the art in view of Tam et al since this would have been the mere substitution of one well known way to deliver a treatment agent and radiation source for another. Tam et al further teaches mixing the treatment agent with a binding agent (column 7, lines 1-5); using more than one treatment agent including radioactive and nonradioactive agents; having different agents disposed in different layers (Figures 4-7 and 9-9A); disposing the radiation source outside the expandable member or within the expandable surface member (column 22, lines 51-59). While embodiments of Williams is directed to cavities created by removing brain tumors, Williams also states that tumors in other sites is also included (column 1, line 64- column 2, line 2); also Tam et al teaches that the device while shown being used in a body lumen is well known to use any other location accessible by catheter which may benefit from radiation delivery including surgically created pathways, esophagus, urethra, ureters, etc. Therefore in view of the teachings to use the device as claimed in claims 27, 31-33 would have been obvious to one skilled in the art since these are well known places within the body to use radiation sources for therapy.

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed 2/12/08 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Williams does not teach a treatment agent releasably mated with an outer surface of the expandable surface member, however Williams was not stated at teaching this. Applicant also argues that Tam does not disclose a treatment agent releasably mated with an outer surface of the expandable surface member and the radioactive source is encapsulated between layers and is not contained within a spatial volume. As pointed out in the above rejection Williams clearly teaches a spatial volume containing a radioactive source that includes a treatment agent that is delivered to adjacent tissue when positioned within a tissue cavity. Williams teaches the claimed device except for the treatment agent being releasably mated with the outer surface of the expandable surface member. Tam was used to provide a teaching of another known radiation device which delivers both a radioactive source and a further treatment agent wherein the treatment agent is releasably mated to the outer surface of the expandable member. Tam clearly provides a teaching of a treatment agent being a coating which is considered to be "releasably mated". The modification of the Williams device would have been obvious since this would have been the mere substitution of one known way to deliver an additional treatment agent

for another. Williams and Tam both teach devices for delivering both radiation source and a treatment agent within the body for therapy.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/  
Primary Examiner, Art Unit 3735